European Medicines Agency

Doc. Ref. EMEA/363648/2009
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EUROPEAN MEDICINES AGENCY DECISION

of 19 June 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a waiver for Colesevelam hydrochloride , Cholestagel (EMEA-000543-PIP01-09) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use as amended and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Genzyme Europe B.V. on 27 February 2009 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 29 May 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a Paediatric Investigation Plan and on the granting of a waiver,

(2) It is therefore appropriate to adopt a Decision granting a Paediatric Investigation Plan.

(3) It is therefore appropriate to adopt a Decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1
[2] OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

Article 1

A Paediatric Investigation Plan for colesevelam hydrochloride, Cholestagel, film-coated tablet, oral use , the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A waiver for colesevelam hydrochloride, Cholestagel, film-coated tablet, oral use , the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Genzyme Europe B.V., Gooimeer 10, 1411 DD, Naarden, Netherland.

Done at London, 19 June 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/313132/2009
EMEA-000543-PIP01-09

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A WAIVER

Scope of the application

Active substance(s):
Colesevelam hydrochloride

(Invented) name:
Cholestagel

Condition(s):
Homozygous familial hypercholesterolaemia
Heterozygous familial hypercholesterolaemia

Pharmaceutical form(s):
Film-coated tablet

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
Genzyme Europe B.V.

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 16(1)of Regulation (EC) No 1901/2006 as amended, Genzyme Europe B.V. submitted for agreement to the EMEA on 27 February 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 2 April 2009.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,

- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annexes and appendix.

London, 29 May 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN AND THE SUBSET(S) OF THE PAEDIATRIC POPULATION AND CONDITION(S) COVERED BY THE WAIVER

A. CONDITION(S)

Homozygous familial hypercholesterolaemia
Heterozygous familial hypercholesterolaemia

B. WAIVER

- **Condition**

  Homozygous familial hypercholesterolaemia

  The waiver applies to:

  – All subsets of the paediatric population from birth to less than 18 years of age

  – for film-coated tablet for oral use

  – on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

- **Condition**

  Heterozygous familial hypercholesterolaemia

  The waiver applies to:

  – Children from birth to less than 10 years of age

  – for film-coated tablet for oral use

  – on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Heterozygous familial hypercholesterolaemia

- **Proposed PIP indication**

Treatment of heterozygous familial hypercholesterolaemia

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 10 to less than 18 years

- **Formulation(s)**

Film-coated tablets for oral use

- **Studies**

Area	Number of studies	Description
Quality	0	Not applicable
Non-clinical	0	Not applicable
Clinical	1	A randomised, double-blind, placebo-controlled, parallel-group, multicentre study of colesevelam administered to paediatric patients with heterozygous FH aged 10 to less than 18 years who are on a stable dose of a paediatric-approved statin monotherapy or who are treatment-naïve to lipid-lowering therapy.

Measures to address long term follow-up of potential safety issues or efficacy in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**Completed in December 2007**
Deferral for some or all studies contained in the paediatric investigation plan:	**No**

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Packaging**	**Content (concentration)**	**Package size**
EU/1/03/268/001	Cholestagel	625 mg	Film-coated tablet	Oral use	bottle (HDPE)		24 tablets
EU/1/03/268/002	Cholestagel	625 mg	Film-coated tablet	Oral use	bottle (HDPE)		100 tablets
EU/1/03/268/003	Cholestagel	625 mg	Film-coated tablet	Oral use	bottle (HDPE)		180 tablets
EU/1/03/268/004	Cholestagel	625 mg	Film-coated tablet	Oral use	bottle (HDPE)		180 tablets